

44231) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical issues. This notice announces the following public meeting of the Diagnostic Imaging Panel (the Panel) of MCAC.

Current Panel Members

Frank Papatheofanis, MD, PhD;
Barbara McNeil, MD, PhD; Carole Flamm, MD, MPH; Jeffrey Lerner, PhD; Michael Manyak, MD; Donna Novak, BA; Manuel Cerqueira, MD; Kim Burchiel, MD; Steven Guyton, MD; Sally Hart, JD; Michael Klein, MBA

Meeting Topic

The Panel will hear and discuss presentations from interested persons regarding FDG Positron Emission Tomography imaging for breast cancer diagnosis and staging.

Procedure and Agenda

This meeting is open to the public. The Panel will hear oral presentations from the public for approximately 1.5 hours. The Panel may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the respective Executive Secretary listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, and submit the following by the Deadline for Presentations and Comments date listed in the **DATES** section of this notice: A brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each panel member prior to offering your public comments. We will request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and HCFA presentations, the Panel will deliberate openly on the topic. Interested persons may observe the deliberations, but the Panel will not hear further comments during this time except at the request of the chairperson. The Panel will also allow approximately a 30-minute open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Panel will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 6, 2001.

Jeffrey L. Kang,

Director, Office of Clinical Standards and Quality, Health Care Financing Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Center Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants. Type of Information Collection Request: NEW. Need and Use of Information Collection: The Mayo Lung Project (MLP) was an NCI-funded randomized collection trial (RCT) of lung cancer screening conducted among 9,211 male smokers from 1971 to 1983. No reduction in lung cancer mortality was observed in the MLP with an intense regimen of x-ray and sputum cytology screening. Recent analysis of updated mortality and case survival data (through 1996) suggests that lesions with little-to-no clinical relevance (over-diagnosis) may have been detected through screening in the MLP intervention arm. Over-diagnosis leads to unnecessary medical interventions, including diagnostic and treatment procedures that carry with them varying degrees of risk. Consequently, over-diagnosis can result in considerable harm, including premature death, which would not have occurred in the absence of screening. The persistence, after screening ends, of an excess of lung cancer cases in the intervention arm is the strongest evidence in support of over-diagnosis, but this information cannot be adequately obtained with available MLP data. Therefore, we propose to re-contact the MLP participants and/or their next-of-kin to determine the participants who were diagnosed with lung cancer after the formal end of the

Project. These data will allow the NCI to either more-convincingly state or perhaps refute the possibility of over-diagnosis in lung cancer screening, and may be used to guide future research agendas and lung cancer screening policies. Frequency of response: Once. Affected public: Individuals. Type of respondents: MLP participants or their next-of-kin. The annual reporting burden is as follows: Maximum number of respondents: 9200; Estimated number of Responses per Respondent: 1. Average Burden Hours Per Response: 0.25; Estimated Maximum Total Annual Burden Hours Requested: 2300. The annualized cost to respondents is estimated at zero. There are no Capital Costs to report. There are no Operating or Maintenance Costs; to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Pamela Marcus, Epidemiologist, Biometry Research Group, Division of Cancer Prevention, National Cancer Institute, Suite 344 EPN, 6130 Executive Blvd, Bethesda, MD 20892-7354; or call non-tool free 301-496-7468; or email pm145q@nih.gov.

Comments due date: Comments regarding this information collection are best assured of having their full effect if received on or before June 29, 2001.

Dated: April 20, 2001.

Reesa L. Nichols,

NCI Project Clearance Liaison.

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